

Appln No. 10/811,690

Amdt date December 13, 2010

Reply to Office action of September 3, 2010

REMARKS/ARGUMENTS

Claims 172-178 and 186 are pending in the above-referenced application.

This is a response to the Office Action dated September 03, 2010 wherein the Examiner rejected claims 172-178 and 186 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,871,785 (Froix) taken in combination with U.S. Patent No. 3,954,644 (Krezanoski) and in view of U.S. Publication No. 2007/0000792 (Newman).

In view of the remarks that follow, reconsideration of the rejections and a notice of allowance are respectfully requested.

**§103(a) Rejection of Claims 172-178 and 186 by Froix taken in combination with
Krezanoski and in view of Newman**

Claims 172-178 and 186 are rejected as unpatentable under §103(a) over Froix taken in view of Krezanoski et al. and in view of Newman.

Of the rejected claims, independent claim 172 recites:

172. (Previously presented) A package system comprising:

a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a hydrophilic polymeric material and a water soluble polymer component;

a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body; and

a container holding the contact lens and the sterile packaging liquid medium, wherein the water soluble polymer component of the cast molded contact lens body and of the sterile packaging liquid medium comprises a polyalkylene glycol.

Thus, claim 172 makes clear that:

- (1) The claimed package system comprises a single use disposable hydrogel contact lens ready for use in an eye and a sterile packaging liquid medium in a container; and
- (2) The contact lens comprises a contact lens body comprising a water soluble polymer component, which comprises a polyalkylene glycol, and claimed sterile

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packaging liquid medium comprises an additional amount of the SAME water soluble polymer component as the one present in the contact lens body.

In rejecting claims 172-178 and 186, the Examiner contends:

The reference to Froix teaches the production of a contact lens material wherein the lens material is polymerized in the presence of a polyethylene oxide (WSP), as herein claimed. . .

The reference to Krezanoski et al (US 3,954,644) show the storage and cleaning of contact lenses using polymers, as herein recited and claimed. . .

The reference to Newman et al (US 2007/0000792) shows a typical package for a contact lens, as herein claimed. . .

. . . As such, the use of the solutions for cleaning/storage with the contact lenses of either primary reference would have been a *prima facie* obvious modification, as being standard in this art. . . The employment of a package, while notoriously obvious since the product must be vended and distributed, or stored prior to distribution, is shown by Newman et al. As such, a skilled artisan would have a high level of expectation of success following the teachings of the references. . . (Instant Office Action, pages 3-4).

As the following remarks will illustrate, Applicant respectfully submits that contrary to the Examiner's assertion, the cited references fail to render the pending claims obvious under §103(a).

The '785 Froix reference

The '785 Froix patent discloses contact lens compositions for the production of contact lenses, including hydrogel contact lenses, "*having satisfactory moisture content but lowered protein absorption*" (Froix, Abstract and Col. 1, line 45 to Col. 2, line 16). Froix's compositions and contact lenses comprise significant amounts of polyethylene oxide (PEO) unit (Froix, Col. 2, lines 36-40).

It should be noted that Froix discloses only compositions comprising either polyethylene oxide or polyethylene glycol having a sub-unit of (CH_2CH_2O) . Froix does not disclose or suggest the use of any other polyalkylene glycols, such as polypropylene glycol, polyoxypropylene, or polybutylene glycol. In fact, Froix makes clear that the repeating PEG or PEO unit is an important factor for the desired characteristics of the lens, as shown below:

The resulting side chains containing repetition of the $-CH_2CH_2O-$ or polyethylene oxide (PEO) unit contribute to the ability of the lens to resist the absorption of protein while retaining a satisfactory moisture content. (Froix, Col. 4, lines 59-63)

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The lenses of the invention, characterized by their water absorbing ability with retention of resistance by their water absorbing ability with retention of resistance to protein absorption, are prepared from compositions which contain significant amounts of the repeating polyethylene oxide subunit –(CH₂CH₂O)_n– wherein n is 1-300. (Froix, Col. 8, lines 25-30).

Thus, Froix makes clear that the desirable properties of Froix's lenses are attributable not to polypropylene oxide, polybutylene glycol, or any other polyalkylene glycols but specifically to polyethylene glycol or polyethylene oxide units.

Froix also teaches the use of block copolymers of the PEG or PEO unit with unsaturated monomers in the disclosed lens compositions (Froix, Col. 5, lines 40-42, and Col. 11, lines 35-49). Examples of unsaturated monomers include styrene, methacrylic acid and acrylic acid (Froix, Col. 11, line 38 and line 48). Unsaturated monomers, as understood to one skilled in the art, include one or more double bonds¹. Thus, Froix's block copolymers of polyethylene glycol or polyethylene oxide with unsaturated monomers do not include Krezanoski's polyoxypropylene-polyoxyethylene block copolymers, as further discussed below.

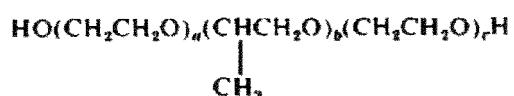
The Examiner relies on Krezanoski et al. to disclose "the use of polyalkylene glycol polymers for storage and cleaning of contact lenses" (instant Office Action, page 3).

The '644 Krezanoski reference

The '644 Krezanoski patent discloses a cleaning solution comprising polyoxypropylene-polyoxyethylene block copolymers with very specific characteristics, including:

...a molecular weight between about 1900 and 15,500, and a water solubility in the excess of about 10 grams per 100ml, a cloud point in 1 percent aqueous solution above about 30C, and a Foam Height in excess of 30 mm; a microbial growth inhibitor, such as benzalkonium chloride. . ." (Krezanoski Abstract; See also Col. 8, lines 29-42).

Krezanoski specifically teaches the use of polyoxypropylene-polyoxyethylene block copolymers in the cleaning solution and further specifies the formula for such compounds as:



¹ <http://chemistry.about.com/od/chemistryglossary/a/unsaturateddef.htm>

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where a and c are statistically equal. (Krezanoski, Col. 8, lines 22-27)

Krezanoski teaches that the disclosed polyoxypropylene-polyoxyethylene block copolymer “*is the primary wetting and cleaning ingredient of the composition*” (Krezanoski, Col. 8, lines 5-7). Krezanoski further teaches that the polyoxypropylene-polyoxyethylene block copolymers when used in an amount from 0.01 to 30 percent of the solution : “*. . . effectively remove proteins, fats, and the mucopolysaccharides that accumulate on the silicone lens surfaces when they come in contact with body tissues and fluids. . .*” (Krezanoski, Col. 9, lines 21-30).

It should be noted that Krezanoski does not disclose or suggest any polymers or copolymers other than the polyoxypropylene-polyoxyethylene block copolymers. It is clear that the desirable cleaning and wetting properties of the cleaning solution are attributable not to any block copolymers but specifically to polyoxypropylene-polyoxyethylene block copolymers .

As described, Krezanoski’s polyoxypropylene-polyoxyethylene block copolymers are used to remove proteins, fats and mucopolysaccharides that accumulate on the lens surface after the lens has been worn. A new contact lens, which has not been used, and stored in a sterile packaging liquid medium, does not have proteins, fats, and mucopolysaccharides accumulated on its surface. Therefore, use of the polyoxypropylene- polyoxyethylene block copolymers is clearly superfluous on an unused contact lens.

Krezanoski specifically teaches the following regimen for using the solution comprising the polyoxypropylene-polyoxyethylene block copolymers:

A typical regimen for a hydrophilic gel lens contact wearer would call for cleaning the lenses immediately after they are removed from the eye with the cleaning composition of this invention, followed by water rinsing of the lenses. The lenses would then be subjected to boiling in normal saline in accordance with conventional procedures to aseptize them. The lenses would be hermetically kept in the normal saline until ready for use. The boiling fluid should contain a protective preservative to provide chemical resterilizing capacity in the event that the seal in the boiling container falls. (Krezanoski, Col. 10, lines 52-62, emphasis added)

Thus, upon contacting or soaking a lens with the Krezanoski solution as suggested by the Office Action, a user needs to: (1) rinse the lenses with water; and (2) boil the lenses in normal saline. Clearly, a contact lens stored in Krezanoski’s solution as proposed by the Examiner

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would not be “ready for use in an eye”, given that it still needs to be rinsed in water AND boiled in normal saline. Thus, contrary to the Examiner’s suggestion, Krezanoski does not disclose or suggest the sterile packaging liquid medium of the claimed package system.

Moreover, the solution is not intended for use with a contact lens designed to be “ready for use in an eye” because of the additional necessary cleaning and boiling steps before the lens could be used. Clearly, such onerous requirements are not commercially economical or viable for a single use disposable hydrogel contact lens ready for use in an eye, as recited by independent claim 172. As such, the suggested combination could not be expected to be within the realm of reasonableness to a person of ordinary skill in the art.

Furthermore, the rinsing of the contact lens in water followed by boiling in normal saline solution as taught by Krezanoski would wash away any water soluble polymer component in the contact lens body. The suggested combination is therefore unworkable and would destroy any benefit intended by including a water soluble polymer component in the contact lens body.

The Examiner relies on the ‘792 Newman publication to disclose a package for a contact lens.

Applicant respectfully submits that the present claims are patentable over the cited prior art for at least the following reasons:

1. The cited references, even if combinable, a position that Applicant does not concede, fail to disclose all the elements of the pending claims; and
 2. A skilled artisan would not have been motivated to combine the cited references in the manner suggested to produce the claimed method.
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1. **THE CITED REFERENCES DO NOT TEACH OR SUGGEST ALL OF THE ELEMENTS OF THE REJECTED CLAIMS**

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"[O]bviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As set forth above, Froix teaches contact lens compositions comprising repeating units of polyethylene glycol or polyethylene oxide. Froix specifically teaches that the repeating PEG or PEO units are important in conferring "*the ability of the lens to resist the absorption of protein while retaining a satisfactory moisture content*". (Froix, Col. 4, lines 59-63). Thus, Froix makes clear that the desirable properties of the lens are attributable, not to any polyalkylene glycols, but specifically to polyethylene glycol (PEG) or polyethylene oxide (PEO) units. Froix also teaches the use of block copolymers of polyethylene oxide with unsaturated monomers, which include one or more double bonds. Thus, Froix's block copolymers of polyethylene oxide do not include Krezanoski's polyoxypropylene-polyoxyethylene block copolymers, which as shown by its structure (reproduced above) do not contain any unsaturated moieties.

As set forth above, Krezanoski discloses a cleaning solution comprising polyoxypropylene-polyoxyethylene block copolymers. Krezanoski explicitly teaches that the polyoxypropylene-polyoxyethylene block copolymer is the primary cleaning ingredient of the composition in that the polyoxypropylene-polyoxyethylene block copolymer effectively removes proteins, fats, and the mucopolysaccharides that accumulate on the worn silicone lens surfaces (Krezanoski, Col. 8, lines 5-7 and Col. 9, lines 21-30). Thus, Krezanoski makes clear that the desirable properties of the cleaning solution are attributable, not to any block copolymers, but specifically to the polyoxypropylene-polyoxyethylene block copolymers having the disclosed structure reproduced above.

As described, notwithstanding the fact that Krezanoski's solution is not a packaging liquid medium, even if erroneously combined, Froix and Krezanoski do not disclose or suggest a contact lens body comprising a water soluble polymer component and a sterile liquid medium comprising an additional amount of the SAME water soluble polymer component, which comprises a polyalkylene glycol.

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Furthermore, according to Krezanoski, after cleaning the lenses with the cleaning solution comprising the polyoxypropylene-polyoxyethylene block copolymer, a user needs to: (1) rinse the lenses with water; and (2) boil the lenses in normal saline. As described, a contact lens stored in Krezanoski's solution as proposed by the Examiner would certainly not be "ready for use in an eye", given that it still needs to be rinsed with water AND boiled in normal saline. The fact that the contact lens after being cleaned with Krezanoski's solution needs to sterilize in a boiling fluid suggests that the solution may not be sterile and possibly even be harmful to the eyes. Furthermore, the regimen taught by Krezanoski would wash away any water soluble polymer component in the contact lens body. Thus, contrary to the Examiner's assertion, Krezanoski does not disclose the sterile packaging liquid medium of the claimed package system.

As Newman is merely relied on to disclose a package for a contact lens, Newman does not cure the deficiencies of Froix and Krezanoski. Notwithstanding the fact that Krezanoski's solution is a cleaning solution that may be harmful to the eye if used without subsequent washing and boiling of the contact lens stored therein, and certainly is not a packaging liquid medium, even if erroneously combined, the combination of Froix, Krezanoski and Newman still fails to disclose all of the elements of the claimed package system. At a minimum, the cited references do not disclose a package system comprising, among other things, a single use disposable hydrogel contact lens ready for use in an eye and comprising a cast molded contact lens body comprising a water soluble polymer component; a sterile packaging liquid medium comprising an amount of the water soluble polymer component in addition to that present in the contact lens body, wherein the water soluble component comprises a polyalkylene glycol, as recited in part in claim 172 (emphasis added).

Since claims 173-178 and 186 depend from claim 172, they are also allowable over the cited references for at least the same reasons.

II. A skilled artisan would not have been motivated to combine the cited references in the manner suggested to produce the claimed method

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Furthermore, a skilled artisan would not have been motivated to combine Krezanoski's cleaning solution with Froix's contact lens in the manner suggested by the Examiner to arrive at the claimed package.

As set forth above, Krezanoski explicitly teaches rinsing a lens that has been in contact with the disclosed solution in water and then subjecting it to boiling saline (Krezanoski, Col 10, lines 55-58). That teaching alone would have discouraged a skilled artisan in the art from using the Krezanoski cleaning solution as a sterile packaging liquid medium, which requires the solution to be safe so that a lens in contact with the solution is ready to be worn. Again, since the Krezanoski solution is not intended for use with a lens that is designed to be "ready for use in an eye" and requires subsequent washing and boiling of the contact lens, the combination suggested by the Examiner would not yield "A package system comprising a single use disposable hydrogel contact lens ready for use in an eye...". Thus, Krezanoski actually teaches away from the claimed package system. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant" *In re Gurley*, 27 F. 3d 551, 553 (Fed. Cir. 1994). Even though the Examiner merely relies on Krezanoski to "show the storage and cleaning of contact lenses using polymers as herein recited and claimed" (Office Action, page 3), "a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention" (§MPEP 2141.02 (VI)). For at least the reason set forth above, a skilled artisan would not have been motivated to combine Froix's contact lens with Krezanoski's cleaning solution to produce the claimed package system.

Furthermore, cleaning solutions and packaging solutions are not viewed as interchangeable by one of ordinary skill in the art. Indeed, there are components that may be suitable for a cleaning solution but not for a packaging solution, as cautioned by Krezanoski:

While many germicidal agents, in appropriate concentrations, demonstrate sterilization of fresh lenses, these same chemicals do not necessarily sterilize a lens worn repeatedly... (Krezanoski, Col. 4: lines 8-10)

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As set forth above, Krezanoski teaches that the intended function of the polyoxypropylene-polyoxyethylene block copolymers, which are the primary ingredient in the disclosed solution, is to facilitate the removal of proteins or other deposits formed on the surface of the contact lens, which accumulate only after the lens has been worn (Krezanoski, Col 9, lines 21-23). In contrast, for an unused contact lens stored in a sterile packaging liquid medium, there is no protein, fat or mucopolysaccharide deposit. For this additional reason, a skilled artisan would not have been motivated to use Krezanoski's solution as a packaging liquid medium.

Furthermore, the fact that the lens needs to be rinsed in water when used with Krezanoski's solution suggests that the cleaning solution may contain chemicals such as disinfectants, which are known to cause eye irritation. In fact, Krezanoski's cleaning solution comprises "a microbial growth inhibitor, such as benzalkonium chloride" (Krezanoski, Abstract, See also Col. 8, lines 29-42). Disinfectants play a vital role in cleaning solutions in that they reduce or eliminate microorganisms or microbial growths to protect the lens wearer from infection. In contrast, for an unused contact lens stored in a sterile packaging liquid medium, there is no need for disinfectants. For this additional reason, a skilled artisan would not have been motivated to combine Krezanoski's cleaning solution with Froix's contact lens to produce the claimed package.

For at least the reasons set forth above, Applicant respectfully submits that a skilled artisan would not have been motivated to combine Krezanoski's cleaning solution with Froix's contact lens to produce the claimed package.

In *KSR International Co v. Teleflex, Inc.*, while emphasizing a more flexible approach to the teaching, suggestion, motivation ("TSM") test, the Supreme Court however acknowledged the importance of "identify[ing] a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does...because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known". *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). "[R]ejections on

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obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex, Inc.*, 550 U.S. at ___, 82 USPQ2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

In rejecting the pending claims over Froix in view of Krezanoski and further in view of Newman, the Examiner merely stated “*Froix teaches the manufacture of the contact lens of the claims. Krezanoski shows the solutions for cleaning/storage using a polyalkylene glycol polymers and show such as conventional, as recited herein. As such, the use of the solutions for cleaning/storage with the contact lenses of either primary reference would have been a facie obvious modification, as being standard in this art.*” (Office Action, page 3).

Applicant respectfully submits that the Examiner has not adequately explained how one of ordinary skill in the art would have been led to package a new and unused contact lens with Krezanoski’s cleaning solution, wherein the primary ingredient is a chemical specifically targeted to facilitate the removal of proteins or other deposits formed on the surface of a contact lens, which accumulate only after the lens has been worn. Likewise, the Examiner has not adequately explained how Krezanoski’s explicit teachings of rinsing the lens in water followed by boiling in saline solution after the lens has been immersed with Krezanoski’s solution would have led a skilled artisan to store a contact lens ready for use in an eye in Krezanoski’s cleaning solution.

Furthermore, the rinsing of the contact lens in water followed by boiling in normal saline as taught by Krezanoski will wash away any water soluble polymer component in the contact lens body. The Examiner has not adequately explained how the combination of Froix’s contact lens with Krezanoski’s cleaning solution would have resulted in the claimed package system, which comprises among other things a hydrogel contact lens ready for use in an eye, the contact lens comprises a contact lens body comprising a water soluble polymer component.

As such, the Examiner has failed to set forth the Graham factors and failed to articulate a reason with rational underpinning to support the legal conclusion that Froix may be combined with Krezanoski to render the pending claims obvious.

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In view of the foregoing, Applicant respectfully submits that the Examiner has not established *a prima facie* case of obviousness and thus the rejection of claim 172 under 35 U.S.C. § 103(a) cannot be properly maintained.

For at least the reasons set forth above, Applicant respectfully submits that the cited references fail to render claim 172 obvious under § 103(a). Since claims 173-178 and 186 depend from claim 172, they too are allowable over the cited references for at least the same reasons.

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CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that claims 172-178 and 186 are patentable over the cited references and allowance is respectfully solicited.

Should the Examiner wish to speak with Applicant's agent, he is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,

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